

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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| Due : <u>11</u> <u>06</u> <u>05</u> mm ii an | INSCRIPTION |
| Goudreau Gage Dubuc PROPRIÉTÉ INTELLECTUELLE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY | VALIDATION |

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(PCT Rule 43bis.1)

Date of mailing 13 May 2005 (13-05-2005)
 (day/month/year)

| | | |
|--|---|--|
| Applicant's or agent's file reference CG/10857.375 | FOR FURTHER ACTION See paragraph 2 below | |
| International application No. PCT/CA2004/002202 | International filing date (day/month/year) 24 December 2004 (24-12-2004) | Priority date (day/month/year) 06 January 2004 (06-01-2004) |
| International Patent Classification (IPC) or both national classification and IPC IPC 7 C08B 37/08 A61K 47/36 | | |
| Applicant UNIVERSITE DE SHERBROOKE ET AL | | |

1. This opinion contains indications relating to the following items :

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(I) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement. |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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| Name and mailing address of the ISA/CA <i>Canadian Intellectual Property Office</i> <i>Place du Portage I, C114 - 1st Floor, Box PCT</i> <i>50 Victoria Street</i> <i>Gatineau, Quebec K1A 0C9</i> Facsimile No: 001(819)953-2476 | Authorized officer <div style="text-align: right;">James Martyn (819) 953-0761</div> |
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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/CA2004/002202

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _
_____, which is the language of a translation furnished for the purposes of international search (under
Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of :
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statement that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments :

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/CA2004/002202

Box No. V Reasoned statement under Rule 43bis.1(a)(I) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|-------------------------------|--------|-----------|-----|
| Novelty (N) | Claims | 5-8 | YES |
| | Claims | 1-4, 9-19 | NO |
| Inventive step (IS) | Claims | 5-8 | YES |
| | Claims | 1-4, 9-19 | NO |
| Industrial applicability (IA) | Claims | 1-19 | YES |
| | Claims | none | NO |

2. Citations and explanations :

D1: CN 1364815 (TAN) 31 Jan. 2002 (2002/01/31), abstract

D2: WO 03/066682 (STRUSZCZYK et al.) 14 Aug. 2003 (2003/08/14), pages 2 and 3

D1 teaches the preparation of a high bulk density chitosan which is prepared by using common chitosan as material by acidification, basification or salting out, dewatering, drying and other steps.

D2 teaches a process for the purification of chitosan comprising the steps of reacting an acidic solution of chitosan with an aqueous base to precipitate microcrystalline chitosan and separating said precipitated microcrystalline chitosan from dissolved proteins to produce a chitosan having a protein content < 10 ppm.

A. Novelty:

The subject matter of claims 1-4 and 9-19 do not meet the requirements of Article 33(2) PCT, (D1: 1-4 and 9-19, D2: 13-19). Claims 5-8 are novel and thus meet the requirements of Article 33(2).

B. Inventive Step:

In view of the lack of novelty in claims 1-4 and 9-19, according to Article 33(2) PCT, these claims also lack an inventive step in view of Article 33(3) PCT. The claimed subject matter of claims 5-8 differ from that of D1 in that specific salts have been selected as well as combinations of 2 or more salts. Additionally, said salt combination consists of a combination of kosmotropic and chaotropic salts. The subject matter of claims 5-8 are considered to comprise an inventive step and therefore meet the requirements of Article 33(3) PCT.

C. Industrial Applicability:

Chitosan has many industrial and biomedical uses. The subject matter of the present application provides a process for obtaining a pure source chitosan. Claims 1-19 therefore have industrial applicability as defined under Article 33(4) PCT.

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made :

A statement in an application, such as found on page 6 paragraph [0020] which incorporates by reference any other document does not comply with Article 5 PCT.

Claims 3, 4, 10 and 11 do not comply with Article 6 PCT. The inclusion of "about" in combination with ranges causes a lack of clarity.

Claim 10 does not comply with Article 6 PCT. The term "several hundreds kDa" causes a lack of clarity.

Claims 13-18 do not comply with Article 6 PCT. The product must be defined by structure, properties and characteristics, independently of the process for its manufacture.

In accordance with Article 5 PCT, all documents referred to in the description of an application must be available to the public. Reference to the document on page 1 paragraph [0002] must be deleted or replaced by its corresponding patent number or publication number.

Claims 17 and 18 do not comply with Rule 6.4 PCT. Claims 17 and 18, which are dependant on claim 12, claim a preparation whereas claim 12 claims a method. Claims 17 and 18 should be dependant on claim 13.

Claim 19 does not comply with Rule 6.3(a) PCT. Claim 19 is directed to the desired result.

Claim 19 does not comply with Article 6 PCT. The expression "such as" attempts to give both a broad and narrow meaning to the scope of the claim.